



# Maximizing the benefits of antiretroviral therapy for key populations

A White Paper by the Key Affected Populations and Treatment as Prevention Working Groups of the International AIDS Society

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## About this paper

“Maximizing the benefits of ART for key populations” grew out of discussions between the Key Affected Populations and Treatment as Prevention Working Groups of the International AIDS Society. The two groups agreed that given the rapidly changing treatment and prevention landscape in HIV, there was a need to consider a range of issues affecting treatment access, prevention choices, and the implications of new guidelines for key populations. While the treatment needs for all persons living with HIV share many commonalities, the reality in 2014 is that access to these essential services differs for key populations in too many

settings. These disparities in access are currently increasing in many countries and contexts. Punitive laws, policies and practices are making it harder to reach the shared global goal of universal access to HIV services for those who need them, and communities at risk are justifiably skeptical that new approaches will be made available with the respect for equity, human rights, and protection from discrimination that are necessary to ensure success. The IAS hopes that this White Paper will be of use to those advocating for and working to realize the right to health, other human rights and full access to essential HIV services for key population groups.

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## Executive Summary

### *There is an expanded clinical and public health rationale for universal access to ART.*

In recent years, scientific research has clearly demonstrated the clinical benefits of earlier initiation of antiretroviral treatment (ART), as well as showing that ART can markedly reduce HIV transmission to sexual partners. These results are reflected in the 2013 global guidance from WHO that recommends initiation of ART at a CD4 count of 500 cells/mm<sup>3</sup> or less, and in certain populations regardless of CD4 count, including people with tuberculosis (TB) and active Hepatitis B (HBV), people with HIV-negative partners and all pregnant women living with HIV. The new recommendations increase the number of people eligible for ART globally from around 17 million under 2010 guidelines to more than 28 million.

### *Universal access must include access for key populations.*

Ensuring universal access to ART for those who need it has long been a core principle of the HIV response, and efforts to achieve this goal must include expanding access for key population groups, defined as men who have sex with men (MSM), sex workers, people who inject drugs (PWID) and transgender people. In many settings, prisoners and migrants are also vulnerable to HIV and face major social and legal barriers to accessing health care. Extending the treatment and prevention benefits of ART to key populations is critical to increasing the impact of ART and the overall effectiveness of the HIV response, but this can only be achieved through an extraordinary effort to address the barriers that key populations face. Concerted and immediate action to dramatically improve the global response to HIV among key populations is urgently required, including through expanded access to ART.

### *Key populations experience disproportionately high disease burden and multiple risk factors in nearly all countries and regions.*

It has long been assumed that key populations represent a modest share of the epidemic globally, and that the prevalence of HIV among them is largely confined to countries with low-level and concentrated epidemics. However, the burden of HIV among key populations in generalized epidemics has been poorly understood due to their limited representation in national surveillance data and the fact that they are stigmatized and criminalized in many settings. Recent analyses show that in nearly all countries and regions, levels of HIV prevalence among MSM, sex workers, PWID and transgender people are far higher than among the general population, and they experience a range of biological, behavioural, social, legal and economic barriers that greatly increase their vulnerability to HIV, as well as to TB and hepatitis.

It is now increasingly recognized that not only do key populations and their sex partners represent most of the people living with HIV outside sub-Saharan Africa, but comprise a significant proportion of new infections in sub-Saharan Africa, as well. As understanding of the dynamics of HIV among key populations in generalized epidemic settings has grown, and as some concentrated epidemics – notably among PWID in Eastern Europe – begin to expand to other population groups, the distinction between concentrated and generalized epidemic settings is becoming less relevant. The needs of key populations can and must be addressed in all countries and regions, regardless of epidemic type.

Prisoners and migrants do not lose their right to health care by virtue of incarceration or moving to seek a better life, and the fulfilment of this right, including access to ART, needs to be seen both as part of countries' obligations to fulfill the right to health of the

population as a whole and as part of effective national responses to HIV and other infectious diseases.

*ART coverage for key populations is alarming low.*

Disaggregated data on ART coverage for specific key population groups are very limited due to neglect, discrimination, weaknesses in national data collection systems and, in some cases, concern that classifying people based on HIV transmission category or membership of a key population group may lead to violations of human rights. Nevertheless, the data that are available reveal low levels of knowledge of HIV status and significant inequities in access to ART among all key population groups, as well as high levels of AIDS-related mortality. For MSM and PWID living with HIV, global ART coverage levels are estimated to be as low as 14% and 4% respectively. Coverage of other tailored prevention interventions for key populations, including harm reduction, is also alarmingly low. Barriers to accessing ART among key population groups are remarkably common, and include fear of disclosure to and negative experiences with health care providers, lack of information about ART, lack of appropriate counselling and outreach services, self-stigmatization and fear of potential legal repercussions of engaging with health services.

*Global policy guidance offers significant opportunities to expand ART access for key populations.*

WHO consolidated guidelines on the use of ARVs for both treatment and prevention, published in 2013, and new, consolidated guidance on HIV among key populations, released by WHO in mid-2014, offer the potential for increased access to HIV testing and counselling and to ART by key population groups.

Although the 2013 ART guidelines recommend that initiation of ART in key populations should follow the same principles as for the general adult population (i.e. at a CD4 count of 500 cells/mm<sup>3</sup>), recommendations that ART should be initiated regardless of CD count in

certain circumstances may be of particular relevance to key populations. These include ART initiation regardless of CD4 count in people with active TB and HIV, HIV and HBV co-infection with severe chronic liver disease, pregnant women, and people in sexual relationships with HIV-negative partners.

The guidelines affirm earlier WHO guidance that HIV testing and counselling should be routinely recommended for key populations in all health facilities in generalized epidemics, and that in low and concentrated epidemics it should be considered in health facilities offering services for sexually-transmitted infections, hepatitis, TB and antenatal care, as well as in health services specifically designed for key populations. Recognizing that many people from key populations may not attend health facilities, the guidelines also recommend that community-based HIV testing and counselling should be available to key populations in all epidemic settings, with appropriate confidentiality and informed consent.

New WHO key population guidance in 2014 recommends that pre-exposure prophylaxis (PrEP) be available as an option for serodiscordant couples and men and transgender women who have sex with men, but there is no specific recommendation for other key populations.

Post-exposure prophylaxis (PEP) has also been used in some countries in key population groups, including MSM and sex workers. While it is an important prevention tool, it cannot substitute for use of other proven prevention methods, including consistent condom use or the use of sterile injecting equipment. However, PEP can be an effective entry point for accessing these methods and other HIV prevention services.

*Rights-based approaches are critical for expanding ART access to key populations.*

Stigma, discrimination and punitive laws, policies and practices significantly limit access to ART and other HIV interventions in many countries, including the 80



countries that outlaw same sex-activity, the more than 100 countries that criminalize some aspect of sex work, those countries that require registration of drug users or that employ predominantly criminal justice - rather than public health - approaches to drug use, and those countries where effective drug dependence treatment is not legally available. Criminalization of HIV non-disclosure, exposure and/or transmission, and failure to legally recognize transgender status, also present barriers to accessing ART in many countries.

Rights-based approaches and investments in critical enablers, such as supportive legal and policy environments, are essential to enable wider access to ART and other HIV interventions for key populations. Such approaches need to include measures to combat stigma and discrimination, repeal punitive laws and practices, mobilize, empower and resource communities and their organizations, and increase the availability of community-based services, including HIV testing and counselling, with adequate links to treatment, care and support. Particular attention is needed to ensure that available services for key populations are equipped to meet the needs of adolescents and young adults.

The primary objective of ART should always be to treat the person living with HIV; prevention is an important, secondary benefit. As with all medical interventions for all people, ART should be provided only with informed consent.

Data collection systems in countries must better address issues for key populations, while always ensuring that the confidentiality, security and human rights of individuals are protected. The international community must also more effectively address trade and intellectual property barriers to ART access, including gaps in the Trade Related Aspects of Intellectual Property Rights (TRIPS) framework, and the threat to ART access posed by so-called "TRIPS-plus" provisions in bilateral "free trade" agreements.

*ART should always be offered in the context of comprehensive HIV care and prevention services.*

The preventive benefits of treatment must not be used as a pretext for failure to provide other necessary HIV programming for key populations, including comprehensive harm reduction and other prevention interventions tailored to meet the needs of PWID, MSM, sex workers and transgender people.

*The needs of key populations and the barriers that they face are well understood. Effective interventions exist. It is time for concerted action.*

Consistent with the Melbourne Declaration of 2014, the international community must act with urgency to ensure that:

- There is sustained advocacy to increase political will and commitment to tackling the global HIV crisis among key population groups;
- Governments prioritize the needs of key populations in national AIDS strategies;
- There is increased domestic and international funding to enhance ART access for key populations, address critical enablers, implement rights-based approaches and reduce legal and human rights barriers to ART access, including criminalization of same-sex activity, sex work and drug use;
- Particular efforts are made to ensure that adequate domestic and/or international resources are available to support interventions for key populations in middle-income countries and emerging economies;



- Expanded access to ART occurs in the context of comprehensive care and prevention, including comprehensive harm reduction and tailored prevention programming for MSM, sex workers and transgender people, recognizing that these approaches are all essential to achieving maximum impact on the epidemic;
- There is recognition that interventions for key populations are most effectively delivered through community- and peer-based organizations, and that these organizations are adequately funded and effectively linked to health services;
- There is increased attention to capturing data on key populations, including population size estimates, through both national systems and community-based efforts that are adequately resourced;
- The international community remains vigilant to ensure that the current attention being paid to key populations by international organizations, donors and advocacy groups is sustained in the post-2015 HIV and development agenda, and translates into expanded programming, enhanced access to ART and greater impact on HIV transmission and HIV and health outcomes for key population groups.



## ***1. New evidence and policy for universal access***

Over the last 20 years, antiretroviral treatment (ART) has achieved remarkable success in delaying HIV-related disease progression and reducing AIDS-related mortality around the world. In 2011, results from the HPTN 052 trial demonstrated that early initiation of ART could also markedly reduce transmission of HIV-1 to sexual partners.<sup>1</sup> Subsequent analyses of the clinical outcomes for treated participants in this landmark trial, reported in March 2014, have clearly demonstrated the clinical benefit to individuals of earlier initiation of therapy, including benefits in reduced morbidity from tuberculosis (TB).<sup>2</sup> Recent population-based studies have further demonstrated that increasing ART coverage can decrease the risk of HIV acquisition at the population level in some of the most affected regions of sub-Saharan Africa.<sup>3</sup> These results are mobilizing the global HIV community to seek accelerated scale-up of earlier ART as both a treatment and a prevention strategy. They have also informed new, consolidated ARV guidelines from WHO that recommend earlier initiation of treatment at or below a CD4 count of 500 cells/mm<sup>3</sup>, a development that markedly increases the number of persons potentially eligible for this life-saving therapy.<sup>4</sup>

A range of approaches has been proposed in response to these developments, including strategies such as “seek, test, treat” that aim to more actively identify and offer testing to people who may be living with undiagnosed - and therefore untreated - HIV infection. At the same time, the treatment as prevention

(TasP) approach recommended by WHO in 2013 aims to maximize the prevention benefits of ART by expanding universal access to ART for all pregnant women living with HIV regardless of CD4 count, and by offering ART to the HIV-positive partner in a serodiscordant couple relationship, also at any CD4 count.

Universal access to ART for those who need and want it has long been a core human rights principle of the HIV response, and now has an expanded clinical and public health rationale. While resources remain an enormous challenge to maximizing the benefits of ART for treatment and prevention and there are a host of operational issues in many, if not all, contexts, the fundamental concept that universal access to ART is a key next step in the global response to HIV is now widely accepted. This is also true for the management and control of global epidemics of TB, multi-drug resistant (MDR) TB and hepatitis C (HCV).

### ***Access for all, including key populations***

Achieving universal access in the coming years necessarily involves addressing the needs of key populations, also called key affected populations (KAP). In this paper, these populations, as currently defined by the International AIDS Society (IAS), have disproportionate burdens of HIV infection, *as well as* low levels of access to essential HIV services. Key populations who share these dual burdens include men who have sex with men (MSM)\*, sex workers

\* “Men who have sex with men” and the corresponding acronym “MSM” refer to all men who engage in sexual and/or romantic relations with other men or who practice same-sex sexual desire. The term is intended to be inclusive of multiple self-determined sexual identities and various identifications with any particular ‘community’ regardless of the large variety of settings/ contexts in which male-to-male sex takes place. It recognizes that there can be common experiences of social exclusion, sexual otherness, marginalization, stigma, discrimination, and/or violence among men who have sex with men, and that there can also be common experiences of support, affinity, love and community.





of all genders, people who inject drugs (PWID) and transgender people. As this paper describes, other populations, such as prisoners and migrants, may also be particularly vulnerable to HIV\*. Although extending the treatment and prevention benefits of ART to these highly marginalized populations will ultimately increase the impact of ART and the effectiveness of the HIV response, it also involves addressing with urgency a wide range of social, political, legal and economic barriers that have until now limited their access to health care, including HIV prevention and treatment.

HIV among key populations is one of the three current, corporate priorities of the IAS. This White Paper is a joint undertaking of the Key Affected Populations Working Group and the Treatment as Prevention Working Group of the IAS, and was developed with the intention of building consensus among IAS members and other stakeholders in the HIV response with regard to treatment access and prevention needs for key populations. The paper aims to describe and analyze the challenges and the barriers that key populations face in accessing and using ART for both treatment and prevention and is intended to provide context to new, Consolidated Guidelines on HIV among Key Populations released by WHO in July 2014.

### **Strategic use of ART for key populations: the science**

There is no evidence to suggest that route of transmission or HIV risk category have any impact on the efficacy of ART as treatment. On the other hand, there is abundant evidence to suggest that, given structural support, treatment adherence for

members of key populations is comparable to other adults in similar treatment contexts. However, the evidence base for efficacy and effectiveness of ART as prevention for these populations does vary. For PWID, data from Vancouver, Western Europe and Australia suggest that early treatment initiation, in combination with an evidenced-based package of other preventive interventions, can be highly effective in controlling HIV transmission and reducing mortality and morbidity.<sup>5,6</sup> While little direct evidence is available for female sex workers, modelling from a number of country and epidemic settings also suggests some prevention benefit of earlier treatment initiation for female sex workers.<sup>7</sup> For sex workers in serodiscordant relationships with primary partners (regardless of which partner is HIV-positive), the benefit of treatment in reducing HIV transmission within these couples has extremely high biological and clinical plausibility.

Findings from a number of studies among MSM suggest a more complex and challenging picture. HIV incidence is rising in many MSM populations in high-income countries despite good access to HIV testing, treatment and clinical care. This is happening even where declines in new HIV infections are being seen for other risk categories, suggesting that the treatment benefits of ART may be compromised among MSM, potentially as a result of high efficiency of HIV transmission and network-level factors, such as a higher proportion of infections due to recent infection.<sup>8</sup> Increasing rates of other STIs, particularly among HIV-positive MSM, may further drive HIV transmission, and have been reported in MSM populations in the UK, US, Australia, the Netherlands, and

\* UNAIDS defines key populations somewhat more broadly than in this paper, as follows:

The term 'key populations' or 'key populations at higher risk of HIV exposure' refers to those most likely to be exposed to HIV or to transmit it – their engagement is critical to a successful HIV response i.e. they are key to the epidemic and key to the response. In all countries, key populations include people living with HIV. In most settings, men who have sex with men, transgender persons, people who inject drugs, sex workers and their clients, and seronegative partners in serodiscordant couples are at higher risk of HIV exposure to HIV than other people. There is a strong link between various kinds of mobility and heightened risk of HIV exposure, depending on the reason for mobility and the extent to which people are outside their social context and norms. Each country should define the specific populations that are key to their epidemic and response based on the epidemiological and social context. (Source: UNAIDS Terminology Guidelines 2011. Available at: [http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2118-terminology-guidelines\\_en.pdf](http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2118-terminology-guidelines_en.pdf))

France.<sup>9</sup> There are virtually no relevant data for transgender people.

Compelling new preliminary data on HIV transmission from the PARTNERS study presented at the 2014 CROI Conference were the first to report on the prevention benefits of treatment in reducing HIV transmissions in male-male couples.<sup>10</sup> The study found that when the HIV-infected member of a couple - gay or straight - was successfully treated and had suppressed viral load, there were no transmissions to primary partners. Uninfected partners were not on PeP or PrEP, and all couples reported at least some inconsistent condom use. These preliminary data suggest that treatment may be as effective for MSM couples as for heterosexual ones. The population level impacts of this finding among male discordant couples - if confirmed in PARTNERS and other studies - remain uncertain and need to be further investigated.

While the prevention benefits of treatment are now clearly established, there will remain a continuing need for a range of comprehensive prevention interventions for key populations, including condom promotion, behaviour change, community empowerment and other rights-based approaches and, in the case of PWID, comprehensive harm reduction. It is essential that governments do not use the preventive benefits of treatment as a pretext for failing to provide these critical interventions, in addition to ART.

### **Overcoming barriers**

Despite this mixed picture and gaps in current knowledge, it is clear that the

challenges faced by key populations in accessing ART stem overwhelmingly from social and cultural attitudes, including stigma and discrimination, and from punitive laws, policies, and practices that present barriers to access. To benefit from ART, people living with HIV must first know their status, and this requires HIV testing and linkage to care in contexts of safety, dignity, and confidentiality. However, in too many countries and contexts, members of key population groups are discriminated against, stigmatized in communities and in health care settings, criminalized, and excluded from essential HIV services, or exclude themselves for fear of legal repercussions.

In 2014, key populations are arguably facing rising threats to accessing care. The recent wave of anti-homosexual legislation and court decisions in Russia, Nigeria, Uganda and India prominently underscores the threats to universal access faced by these populations and is illustrative of the fundamental challenges involved in extending the benefits of ART access to those who need it in most regions of the world.

It should not be assumed that because the scientific community has now reached consensus on the benefits of earlier treatment initiation, that ART will become genuinely available to key population groups without extraordinary effort. Concerted and immediate action to dramatically improve the global response to HIV among key populations is urgently required, including through expanded access to ART.

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## 2. HIV burden and risk factors among key populations

It has long been assumed that key populations represent a modest share of the HIV epidemic globally and that the prevalence of HIV among them is largely confined to countries with low-level and concentrated epidemics. However, the burden of HIV among key populations in generalized epidemics has been poorly understood due to their limited representation in national surveillance data and the fact that they are criminalized, hidden and stigmatized in many settings. It is now increasingly recognized that not only do key populations and their sex partners represent most of the people living with HIV outside sub-Saharan Africa, but a significant proportion of new infections in sub-Saharan Africa as well,<sup>11,12</sup> including up to half of new infections in Nigeria,<sup>13</sup> a third in Kenya<sup>14</sup> and 28% in Mozambique.<sup>15</sup>

As understanding of the dynamics of HIV among key populations in generalized epidemic settings has grown, and as some concentrated epidemics – notably among PWID in Eastern Europe – begin to expand to other population groups, the distinction between concentrated and generalized epidemic settings is becoming less relevant. The needs of key populations must be addressed in all countries and regions, regardless of epidemic type.

### **Men who have sex with men**

Globally, epidemics of HIV are continuing to expand among MSM, and high numbers of new infections are consistently found among them in nearly all contexts studied.<sup>16</sup>

Very high prevalence levels are found in North America, South and South East Asia (up to 15%), sub-Saharan Africa (up to 18%) and the Caribbean (up to 25%), with rates in other regions ranging from 3% in the Middle East and North Africa to around 10% in East Asia. Surveillance data in low- and middle-income countries have found that MSM are more than 19 times more likely to be living with HIV than the general population.<sup>17</sup> In many high-income settings, including Australia, France, the UK and the USA, overall epidemic trends are in decline, *except* among MSM. New HIV incidence data from several countries, including Thailand, Kenya and among black MSM in several US cities, show consistently high numbers of new infections, with the highest rates of HIV acquisition occurring among the youngest age groups.<sup>12</sup>

A significant HIV epidemic appears to be established among MSM in China, with one estimate showing that MSM now account for more than a third of new infections in the country.<sup>18</sup> Projections indicate that MSM could make up half or more of all new infections in Asia by 2020.<sup>19</sup>

Individual level risks for HIV acquisition in MSM include unprotected receptive anal intercourse, high frequency of male partners and high number of lifetime male partners, injecting drug use, high viral load in the index partner, African-American ethnic origin (in the USA) and non-injecting drug use, such as use of amphetamine-like

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stimulants. However, individual-level risks are increasing recognized as inadequate to account for persistently high transmission rates among MSM, especially in the era of ART. Network-level effects may also be important, as larger sexual networks provide more opportunity for exposure, and HIV can be transmitted through large networks at great speed, in part due to the high risk of transmission attributed to recent infections in many settings. As many MSM may also have sex with women, their female sexual partners are also at risk. Structural factors that limit access to and uptake up health services, including denial, lack of knowledge of HIV status, stigma, self-stigmatization, discrimination and criminalization, significantly increase the vulnerability of MSM.<sup>20</sup>

HIV prevention efforts among MSM have focused significantly on behavioural change to reduce sexual risk, alcohol and substance use and the number of sexual partners, while increasing condom use. Although these have yielded many successes, they have not been sufficient to contain the epidemic among these populations. Biomedical approaches are increasingly emphasized in combination with behavioural interventions, including adherence to ART as a preventive measure and oral pre-exposure prophylaxis.<sup>21</sup> In many countries, however, coverage of HIV prevention interventions for MSM is grossly inadequate and access to health services - including HIV testing and ART - is limited by discrimination, stigma, punitive laws and practices, and lack of community empowerment.<sup>22</sup>

### Sex workers

Female sex workers have been reported to be at high risk of HIV infection in nearly every setting where they have been studied. A systematic review and meta-analysis by Baral and colleagues in 2012 estimated global burden among female sex workers in 50 countries to be 11.8%, with regional estimates ranging from 1.7 % in the Middle East/North Africa to 36.9% in sub-Saharan Africa.<sup>23</sup> Extraordinarily high prevalence levels among female sex workers have been reported in a large number of sub-Saharan African countries, including 71% in Malawi, 61% in Zimbabwe, 60% in South Africa, 45% in Kenya, 40% in Benin, 37% in Uganda and Guinea, 36% in Togo, 30% in Cameroon and 24% in Rwanda. In these countries, sex workers are estimated to account for between 2.5% (Rwanda) and nearly 80% (Togo) of all new HIV infections. Overall, female sex workers in this region have more than 12-times increased odds of living with HIV as compared to all women.

High HIV prevalence levels among female sex workers have also been reported in Asia, including 23% in Cambodia, 17% in Papua New Guinea, 14% in India, 12% in Thailand and 11% in Malaysia. In China, India, Malaysia and Nepal, sex workers account for between a quarter and two-thirds of all new infections. High prevalence is also reported in countries in other regions, including 28% in Guyana, 13% in Ukraine and more than 5% in Somalia. While countries in the Middle East and North Africa have a relatively lower HIV prevalence among sex workers, they may account for a high proportion of new infections, estimated by Baral and colleagues at 36% in Egypt and 30% in Somalia.

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Although HIV burden among sex workers may vary depending upon geographical epidemic typology, the way sex work operates in a particular setting, and overlapping risk behaviours such as injecting drug use, the behavioural, biological, biomedical and structural risks that sex workers face are similar in most settings. Behavioural risk factors include high-risk sexual exposures and high numbers of sexual partners, while biological factors include the high prevalence of STIs reported among sex workers. Structural factors may include limited access to health, HIV and STI services, poverty, discrimination, gender inequality, risk of sexual violence, and legal and regulatory policies that criminalize sex work and reduce sex workers' capacity to negotiate safer sex and their access to health care.

Most sex workers worldwide are women, but significant populations of male and transgender sex workers exist in many countries and relatively little research has been undertaken among them. It is however likely that they are at increased biological risk due to high per act transmission probability through unprotected anal intercourse, high prevalence of HIV in some subgroups of MSM, and large proportions of male and transgender sex workers who report bisexual behaviour.<sup>24</sup>

Interventions that address behavioural and structural factors have proven successful for increasing protective behaviours and decreasing HIV and STI transmission among female sex workers. In most settings, consistent condom use and HIV testing are higher among sex workers than among women in the general population. Of 87 countries reporting to UNAIDS in 2010, 44

reported that over 80% of sex workers used a condom with the last client, but ongoing HIV prevention programmes reach less than half of sex workers worldwide.<sup>25,26</sup>

WHO recommends that programmes for HIV among female sex workers should include promotion of correct and consistent condom use among sex workers and their clients, periodic screening for asymptomatic STIs, presumptive STI treatment in settings with high STI prevalence and limited clinical services as a short term measure while comprehensive services are developed, voluntary HIV testing and counselling, ART consistent with WHO guidelines for adults and adolescents, and catch-up HBV immunization strategies in settings where infant immunization has not reached full coverage.<sup>27</sup> Such programming should be consistent with rights-based approaches and include structural interventions, such as working towards decriminalization of sex work, implementing anti-discrimination laws, providing accessible and acceptable health services, addressing violence against sex workers and empowering sex worker organizations.

### **People who inject drugs**

Injecting drug use has been reported in 151 countries, and there are an estimated 16 million PWID worldwide, 3 million of whom are living with HIV.<sup>28</sup> PWID account for roughly one third of all new HIV infections outside sub-Saharan Africa, and prevalence of HIV among PWID is at least 22 times higher than for the population as a whole, according to data collected by UNAIDS from 49 countries. HIV epidemics among PWID are increasing in severity across Eastern Europe

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and Central Asia, making this one of the few geographic regions worldwide where the HIV epidemic is still expanding.<sup>29</sup>

A lack of access to sterile injecting equipment is also a driver of other blood borne viruses, notably HBV and HCV. PWID generally bear significantly higher burdens of these two diseases than of HIV: between 60% and 80% of PWID living with HIV worldwide are co-infected with HCV.<sup>30</sup> Since PWID are also at high risk for incarceration and detainment in other overcrowded settings, they also have very high burdens of TB.

In addition to the need for the prevention and treatment of HIV, HCV and TB for PWID, PWID who inject and are dependent on opiates need access to voluntary, rights-based opioid substitution therapy (OST) programmes. OST can have easily manageable interactions with drugs to treat HIV, TB or HCV.<sup>31</sup>

Taken together, these prevention and treatment needs for PWID suggest they are a critical priority population for HIV and health services. Yet they are arguably the least served. This paradox is partly a function of data availability, since for many key populations there is little population-specific data on treatment or access to services, but it is overwhelmingly the result of criminalization and stigmatization.

There is, encouragingly, a wealth of data to demonstrate that where PWID have sufficient access to sterile injecting equipment, evidence-based drug dependence treatment on demand, and ART with adherence support for those living

with HIV, HIV transmission among PWID can be virtually eliminated.<sup>32</sup> Individual level benefits for a person who seeks drug treatment for opioid dependency include improved functioning in daily life and, for those living with HIV, improved adherence to ART and improved clinical outcomes.<sup>31</sup> OST has also been shown to have social benefits, including reductions in crime and other social harms.<sup>33</sup> The evidence is also clear that outcomes for PWID on ART are similar to those of other populations when supportive and comprehensive harm reduction services, OST on demand and non-punitive, non-stigmatizing approaches to service provision are available.

As in the case of perinatal transmission, the available interventions and technologies to control the HIV epidemic among PWID and to expand their access to ART are understood and adequate. However, stigma, discrimination and punitive laws, policies and policing practices are the principal barriers to achieving greater impact.

### **Transgender people**

Transgender women, defined as people assigned male gender at birth but who identify as women, have also long been known to be at high risk of HIV infection. As with other key population groups, national surveillance systems have not captured data on the burden of HIV among transgender women. A meta-analysis by Herbst and colleagues reported an average prevalence of 27.7% from four US studies that reported laboratory-confirmed results, with far higher prevalence among African-American transgender women (56.3%) than those who were white (16.7%) or Hispanic (16.1%).<sup>34</sup> The study

The available interventions and technologies to control the HIV epidemic among PWID and to expand their access to ART are understood and adequate. However, stigma, discrimination and punitive laws, policies and policing practices are the principal barriers to achieving greater impact.



suggests that many transgender women in the US are unaware of their status. Another meta-analysis by Operario and colleagues in 2008 found a crude HIV prevalence among transgender women engaged in sex work in 13 countries of 27.3% and 14.7% among non-sex worker transgender women.<sup>35</sup> Although transgender women sex workers were more than four times likely to be living with HIV than female sex workers, very few interventions are tailored to their needs.

A meta-analysis by Baral and colleagues in 2012 found pooled HIV prevalence among transgender women of 19.1% in the 15 countries with available data, disaggregated to 17.7% in low- and middle-income countries and 21.6% in high-income countries.<sup>36</sup> Extremely high HIV prevalence was found among transgender women in India (44%), Peru (29%), Argentina (33.5%), Indonesia (26%) and Italy (24.5%). The analysis noted remarkable consistency in the severity of disease burden among transgender people across all regions, notwithstanding the wide cultural and social variability of transgender communities and of the political and legal contexts in which they live. As in the case of MSM, a primary driver of HIV infection is the high transmission probability of unprotected receptive anal intercourse, as well as network-level risks such as high HIV prevalence among gay, bisexual and other MSM in the countries included in the analysis, some of whom might also partner with transgender women.

In most countries, access to gender-affirming procedures, such as hormonal treatment and surgical interventions, is dependent on exclusionary requirements such as psychiatric

diagnosis, legal permission and/or the person's ability to pay. Other forms of body modification, such as silicon pumps, industrial oil injections and hormonal treatment without clinical supervision had an overall negative impact on transgender women's health.<sup>37</sup>

While data on HIV risks and prevalence among transgender men (female-to-male transgender persons) are limited, recent studies challenge the assumption that their risks are low, with one study in New York City<sup>38</sup> reporting 6% prevalence among this population and another in San Francisco reporting similar prevalence among transgender men (10%) and transgender women (11%).<sup>39</sup> Transgender men who identify as gay or bisexual, or those who have sex with cis men\* face increased risks due to factors such as fear of violence or rejection from potential sex partners, low self-esteem, transition-related sexual exploration and desire for validation as gay or bisexual men.<sup>40</sup> Testosterone can affect histomorphology of vaginal tissue, making it less flexible and more fragile.

Access to health care in general is challenging for both transgender men and women due to lack of recognition and respect for their gender identities and expressions, lack of training among health care providers on transgender health issues, and intersectional discrimination including race and class that is frequently associated with real or perceived status as sex workers, homeless, living with HIV, migrants or drug users.

Early HIV programming based mainly on behaviour change for transgender women has had mixed success. A 2014 analysis of programming for transgender women

Access to health care in general is challenging for both transgender men and women.

\* Men whose gender identity matches the gender identity assigned to them at birth.



emphasized the relative effectiveness of HIV testing and counselling through mobile outreach, prevention provided in safe spaces and through peer outreach, and a comprehensive package of interventions including community engagement and empowerment, STI treatment, condom and lubricant distribution, community mobilization and advocacy for an enabling and gender-affirming environment.<sup>41</sup>

### ***The vulnerability of prisoners and migrants***

While prisoners and migrants are not included in the definition of key populations used in this paper, both incarceration and migration involve a range of behavioural, social and structural factors that may increase the risk of HIV transmission in these settings as well as reducing access to and continuity of HIV treatment and prevention services, including ART. Due to criminalization, these populations are also disproportionately represented in prison populations in many countries.

In nearly all countries, **incarcerated populations** have a higher risk of acquiring and transmitting HIV, HCV and TB, including through alcohol and injecting drug use, untreated mental illness, lower socioeconomic status and belonging to an ethnic minority group.<sup>42,43</sup> Conversely, these factors also contribute in many settings to increased likelihood of incarceration.<sup>44</sup>

Reviews of HIV prevalence in prisons show that, in nearly all regions and countries, HIV prevalence is several times higher than in the community outside prisons.<sup>42</sup> This is due in part to high rates of incarceration among people who inject drugs, with studies from

a large number of countries showing that between 50 and 90 per cent of people who inject drugs had been imprisoned at some stage, as well as the high proportion of prisoners incarcerated for drug-related offences. While data on the number of people living with HIV who are incarcerated are scarce, in the five countries with the largest HIV epidemics among people who inject drugs (China, Russia, Malaysia, Ukraine and Viet Nam), many people who inject drugs are detained or incarcerated.<sup>45</sup> According to the US Centers for Disease Control, an estimated 1 in 7 people living with HIV in the United States pass through a correctional facility each year.<sup>46</sup>

In addition to HIV, high levels of other STIs and HCV are also widely reported in many prison settings. In all regions, prisons present a high risk of transmission of these diseases through high-risk behaviours such as consensual sex, rape, tattooing, piercing and needle reuse.<sup>47</sup> Injecting drug use in African prisons, often overlooked, has reportedly been increasing.<sup>48</sup> TB and HIV frequently occur together in prison settings. TB in prisons can constitute up to 25% of a country's overall disease burden, and the rate of TB among incarcerated populations is as many as one hundred times higher than that found outside prisons. In many countries TB is one of the leading causes of death among prisoners.<sup>49</sup> TB transmission in prisons is greatly facilitated by overcrowding and poor ventilation. Poor medical services and inconsistent access to and use of medication have led to high rates of MDR-TB in prisons in many countries, especially in the former Soviet Union, southern Africa and parts of Asia.<sup>50</sup> The impact of TB in prisons extends beyond the prison walls: research in Zambia has





associated high TB rates in prisons with higher than expected TB prevalence in the surrounding community.<sup>44</sup> Another study found that increases in rates of incarceration accounted for nearly three-fifths of the average total increase in national TB incidence in 26 countries in Eastern Europe and Central Asia.<sup>51</sup>

Few countries implement comprehensive HIV and HCV prevention, treatment and care programmes in prisons, often because of ideological objections or denial about sex and drug use among prisoners. Fewer than 10 countries are currently providing some form of access to sterile needles and syringes in prisons.<sup>52</sup> Many countries also fail to provide access to TB screening, immunization or active case-finding programmes in prisons and to adequately link prison health services to national HIV, TB or public health programmes.<sup>53</sup> Prison health is frequently disregarded because Ministries of Interior or Justice, rather than Ministries of Health, are responsible for prison health services.

Numerous reports by independent investigators, including the UN Special Rapporteur on Torture, have found that human rights abuses and lack of access to medical care in prison settings, including lack of access to pain relief and drug dependence treatment, may represent cruel, inhuman and degrading treatment.<sup>54</sup> Such abuses are starkly evident in the notorious detention centres in several countries in Asia - including China, Vietnam, Cambodia, Laos and Thailand, in which large numbers of people, including people who use drugs, sex workers, MSM and transgender people, are arbitrarily

detained for lengthy periods in the name of “rehabilitation” or “treatment”, and are subject to forced labour and other rights abuses, including lack of access to adequate health care.<sup>55</sup>

The high prevalence of HIV, TB and HCV in prison settings cannot be separated from broader public health concerns, and the fulfillment of the right to health of people in prisons needs to be seen as a part of state obligations to fulfill the right to health of the population as a whole.

WHO and UNODC recommend that comprehensive prison-based programmes should include HIV information and education; condoms and water-based lubricant; needle and syringe programmes; post-exposure prophylaxis for sexual assault and other exposures to HIV; HIV testing and counselling; OST for opiate dependence; ART and related clinical care; prevention, diagnosis and treatment of TB; prevention of mother-to-child HIV transmission; prevention and treatment of STIs; vaccination, diagnosis and treatment of viral hepatitis, and measures to prevent sexual violence and reduce the reuse of tattooing equipment.<sup>53</sup> Alternatives to incarceration that approach drug use as a health, rather than a criminal issue, are important structural interventions.

If incarcerated, transgender people should be placed in detention facilities according to their gender identity, granted adequate protection other than by means of solitary confinement, and have adequate access to gender-affirming procedures, including hormone therapy.

The high prevalence of HIV, TB and HCV in prison settings cannot be separated from broader public health concerns, and the fulfillment of the right to health of people in prisons needs to be seen as a part of state obligations to fulfill the right to health of the population as a whole.



Internal or transnational **migrant populations** have generally not been included in the definition of key populations because they may have lower, similar or higher burdens and risks for HIV than populations in host countries. However, migrants generally experience low access to HIV services, face a range of barriers to accessing services and staying in care, and may face added stigma, discrimination and “blaming” around migrant status and HIV that are particular threats to their health and safety. Some migrants, including migrant sex workers, people who use drugs or men who have sex with men, may face overlapping risks for lower access to services due to both migrant status and as part of stigmatized and/or criminalized populations.

Refugees are defined in international law as “persons who have fled across an international border and have a recognized international legal status that should enable them to receive access to medical care on an equivalent basis to host nationals in their countries of asylum.<sup>56</sup> Given potential obstacles such as language barriers, lack of employment and risk of further displacement to other countries<sup>57,58</sup>, concerns exist about whether refugees who have initiated ART are sufficiently stable and therefore capable of sustaining optimal adherence and viral suppression. In some cases, governments may be reluctant to provide HIV treatment and care to refugees<sup>59</sup>, citing concerns about stability and the priority of supplying medications to their own citizens.<sup>60</sup>

The Global Commission on HIV and the Law reviewed the status of migrants and access to HIV services and estimated that in 2012 there were some 214 million international

migrants worldwide, and 740 million internal migrants.<sup>61</sup> International migrants include documented labourers, undocumented persons leaving homelands for a range of reasons - from economic hardship to conflict and persecution - and include adults and children, men and women, and persons living with HIV in need of treatment and care services. The Commission was clear in its findings for migrant populations: “In matters relating to HIV and the law, countries should offer the same standard of protection to migrants, visitors and residents who are not citizens as they do to their own citizens.” The reality is that migrants in most countries do not have equal access to health care or adequate standards of legal protection.

Legal factors may exacerbate vulnerability of migrants to HIV and to lack of HIV services. These include lack of entitlement to health services for legal and/or undocumented migrants in some countries, and the concern that disclosure about HIV will adversely affect legal status or visa application processes. Many countries with large populations of migrant labourers conduct mandatory testing for HIV and expel labourers living with HIV, a common practice in the Gulf States.

Migrants from high prevalence countries may have higher likelihoods of HIV infection than host country nationals in some settings, while in others they may be moving from very low prevalence contexts to higher prevalence ones, increasing the need for HIV prevention services for migrants at risk. Frequently, however, migrants are more often prosecuted and vilified for HIV transmission and exposure than other groups, as reported in Denmark, Estonia, Finland, Sweden and the UK.<sup>62,63</sup>

People who have left their countries of origin to flee conflict, to work or to seek a better life do not lose the human right to health care. Migrant populations cannot be excluded from accessing services if the global HIV pandemic is to be controlled.



An example of the complexity of migration and HIV issues is the large and longstanding population of migrants and refugees from Burma/Myanmar who are resident in Thailand. While Thailand was the first country in Asia to commit to universal access to ART for its citizens, that commitment has not extended to the estimated 1-2 million migrants from Burma/Myanmar, who labour in Thailand's farms, factories, homes, fisheries and in the extensive Thai sex industry. While over 500,000 labour migrants from Burma/Myanmar do have some form of labour registration that in theory should enable them to access health services, many more do not have any legal status. While Thai authorities have prioritized HIV prevention services for migrants in Thai-Burmese

border areas, a range of barriers has been identified that limit the uptake of services. These include mobility, language, illiteracy and traditional customs among migrant people, families and communities.<sup>64</sup> The large numbers of Zimbabweans who have migrated across southern Africa face similar barriers to accessing services.

People who have left their countries of origin to flee conflict, work or seek a better life do not lose the human right to health care, and migrant populations cannot be excluded from accessing services if the global HIV pandemic is to be controlled.



### 3. Coverage of antiretroviral therapy for key populations

Disaggregated data on ART coverage for specific key populations are very limited due to neglect, discrimination, weaknesses in national data collection systems and, in some cases, risks that classifying people based on HIV transmission category or membership of a key population may lead to violations of human rights. Nevertheless, the data that are available reveal significant inequities in access to ART for all key populations.

#### Men who have sex with men

Data on access to both HIV treatment and prevention services for MSM are very limited. The percentages of MSM who do not know their HIV status are estimated to be 36% in Europe, Central Asia and Latin America and the Caribbean, 74% in Asia and above 70% in the few sub-Saharan African countries for which data are available, suggesting that ART coverage is also likely to be very low.<sup>65</sup> A biennial online survey of 1000 MSM conducted by the Global Forum on MSM and HIV in 2012 revealed that access to treatment among those who were HIV-positive ranged from 14% in low-income countries to 51% in high-income countries.<sup>66</sup> Access to condoms, condom-compatible lubricant and HIV testing was also poor among survey participants from low- and middle-income countries and did not exceed 54% among those in high-income countries. Focused interventions of any kind for MSM in sub-Saharan Africa are extremely rare.<sup>67</sup> Black MSM in the United States are reported to be less likely to take ART than white MSM.<sup>68</sup>

A modelling exercise by Beyrer and colleagues in 2012 estimated that 20-25% reductions in HIV incidence among MSM worldwide could be achieved with significantly increased investments and coverage of pre-exposure prophylaxis for MSM - averting 0.5-1 million new infections among MSM over 10 years - and ART, averting 75,000 infections in one year alone.<sup>69</sup>

#### Sex workers

Few data are available on ART coverage for sex workers. However, rates of knowledge of HIV status are also very low, ranging from 40% among sex workers in sub-Saharan Africa to only 16% in Asia, suggesting that treatment coverage for this population is also low.<sup>65</sup> A systematic review of interventions to reduce HIV transmission among sex workers in sub-Saharan Africa by Chersich and colleagues found no studies that aimed to improve treatment access, out of 26 that met the inclusion criteria.<sup>70</sup> The few studies that have examined AIDS-related mortality in sex workers show that they are less likely than other women to receive timely and adequate HIV treatment and care.<sup>71</sup> A study in India found that the rate of AIDS-related mortality among female sex workers was 10 times higher than the national mortality rate among women of a similar age, and that less than half of those who had died had been on ART.<sup>72</sup> The study notes that while there are no published data in India on the number of female sex workers receiving ART through the national program, community organizations in

While disaggregated data on ART coverage for key populations are limited, they reveal significant inequities in access.

Chennai report limited access and barriers that included fear of disclosure, lack of family support, negative experiences with health care workers, lack of counselling and outreach workers, lack of knowledge about ART and fatalism about HIV.

Persistent gaps in access to ART, delayed initiation and challenges in treatment retention have been reported in a study among marginalized populations of sex workers in Vancouver, Canada, despite extensive efforts to expand ART access. Of 74 ART-experienced sex workers followed for 2.5 years (2010-2013), 38% reported treatment interruptions. Factors associated with treatment discontinuation included migration, mobility and incarceration.<sup>73</sup>

Despite low levels of ART coverage, sex workers who did access ART in Kenya were reported to have good treatment outcomes and there was no association between ART and increased sexual risk behaviours.<sup>74</sup> One study has estimated that expanding treatment access to female sex workers in Kenya could reduce the number of female sex workers acquiring HIV by 25%.<sup>75</sup>

### **People who inject drugs**

PWID have among the lowest treatment and prevention coverage of any population at risk for HIV infection, including in countries where this group represents most of the population living with HIV. A global analysis estimated that only 4% of people living with HIV who inject drugs worldwide were receiving ART, at a time when ART coverage among all people living with HIV globally was 18%.<sup>76</sup> In 2008, in the five countries with the largest HIV epidemics among PWID, PWID accounted

for 67% of HIV cases, but only 25% of those receiving ART.<sup>45</sup> Slightly improved but still low levels of ART access for PWID were reported between 2010 and 2012 in China (where around 10% of PWID access ART), Malaysia (5%) and Ukraine (5%).<sup>29</sup>

Global coverage of key prevention interventions for PWID is also extremely low: an estimated two needle-syringes are distributed per PWID per month and only around 8% of PWID globally receive OST.<sup>76</sup>

Among the 19 countries in the WHO EURO region, an average 21% of people receiving ART reported that they acquired HIV through a lack of access to sterile injecting equipment, a figure that is prone to underreporting.<sup>71</sup> A prospective cohort study in Ukraine found that pregnant women who injected drugs were less likely to receive ART than those who did not.<sup>77</sup>

Access to ART for PWID may be improving in some Asian countries. In Vietnam, for example, as many as 73% of people receiving ART in a study in Ho Chi Minh City reported a history of injecting drug use. However, as a study in 2013 reported, many countries know that they have a high prevalence of HIV-positive PWID but do not attempt to measure ART coverage, and coverage in most countries remains very low. Of the 21 countries studied, estimates of ART coverage for PWID were available for only 10, and ranged from 0.06% in Afghanistan to 22% in Bangladesh.<sup>78</sup>

Alarming, more than a quarter of health care providers in Canada and the US have stated that they would “defer” ART even at a CD4 count of 200 cells/mm<sup>3</sup> if



a patient actively injects drugs, and more than half would “defer” ART if a patient injects daily.<sup>79</sup>

### **Transgender people**

As with other key population groups, data on ART access for transgender people are scarce, as sex disaggregation does not take account of transgender status. High HIV prevalence, low knowledge of serostatus and poor access to interventions of all kinds among transgender people suggest that ART coverage is also extremely low. A study in Chennai found that many transgender women feared serious adverse consequences if their HIV-positive status were revealed to others.<sup>80</sup> Strong motivations to conceal one’s HIV-positive status were interconnected with prejudice based on gender identity and expression, sexual orientation, sex work and HIV stigma prevalent within families, the health care system and society at large. HIV stigma was present within transgender communities as well. Consequences of disclosure, including rejection by family, eviction from home, social isolation, loss of subsistence income, and maltreatment within the health care system, presented powerful disincentives to accessing ART.

ART may present a more complicated side effect profile in the case of people taking hormone therapy, and there is some evidence that, where such services are available, transgender women may prioritize transition-related health care over ART.<sup>81</sup>

A US study found that transgender women were less likely to have received ART compared to non-transgender participants (59% v 82%) and that transgender women

have higher HIV-related mortality and higher community viral load compared to non-transgender people.<sup>82</sup> A study of transgender women on ART in four US cities found that such women were less likely to report 90% adherence rates, had less confidence in their abilities to integrate treatment regimens into their daily lives and had significantly fewer positive interactions with health care providers than other people.<sup>81</sup> There are virtually no data available on ART access and outcomes for transgender men.

Consequences of disclosure, including rejection by family, eviction from home and maltreatment within the health care system present powerful disincentives to accessing ART.



## 4. Global guidance on ARVs for treatment and prevention among key populations

WHO consolidated guidelines on the use of ARVs for both treatment and prevention, published in 2013, and new, consolidated guidance on HIV among key populations, released by WHO in mid-2014, offer the potential for increased access to HIV testing and counselling, and to ART, for key populations.

### Antiretroviral treatment

The WHO Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection<sup>4</sup> combine new and existing guidance on ARV use in all age groups and populations - adults, pregnant and breastfeeding women, adolescents, children and key populations - for both treatment and prevention. New clinical recommendations promote expanded eligibility criteria for ART with a CD4 threshold for treatment initiation of 500 cells/mm<sup>3</sup> or less for adults, adolescents and children. The guidelines provide that priority should be given to individuals with severe or advanced HIV disease and those with CD4 count of 350 cells/mm<sup>3</sup> or less.

Consistent with earlier WHO guidance<sup>83,84</sup>, the 2013 guidelines provide that the initiation of ART in key populations should follow the same principles as for the general adult population i.e. in general, ART should be initiated at a CD4 count of 500 cells/mm<sup>3</sup> or less. However, recommendations that ART should be initiated *regardless of CD4 count* for people in certain circumstances may have particular relevance to key population groups.

These recommendations include:

- Initiation of ART regardless of CD4 count in people who have HIV and active TB, and people with HIV/HBV co-infection and severe chronic liver disease. Such groups are likely to include people who inject drugs, prisoners and migrants, among others;
- Initiation of ART regardless of CD4 count in all pregnant women. This would obviously include pregnant sex workers living with HIV, women with HIV who inject drugs, prisoners and migrants, among others;
- Initiation of ART in all people in serodiscordant relationships to reduce the risk of HIV transmission to the HIV-negative partner. Serodiscordant relationships are likely to include many people from key population groups in all regions of the world. Male same-sex serodiscordant couples would be included in this recommendation.

WHO estimates that more than 28 million people living with HIV globally have become eligible for ARV drugs under the 2013 guidelines, compared with 17 million under the 2010 guidelines. While the proportion of the additional 11 million eligible people who are from key populations has not been estimated, it is plausible that the new guidelines could help to expand access to ART for both treatment and prevention for key populations. Notably, accompanying operational recommendations by WHO aim to promote decentralized ART services. These provide that in settings with high burdens



of TB and HIV, ART should be initiated in TB treatment settings with ongoing links to HIV care; that ART should be initiated and maintained in care settings where OST is provided, and, that in generalized epidemic settings, ART should be initiated and maintained in pregnant and postpartum women in maternal and child health care settings, with appropriate links to ongoing care.

However, in many countries, these recommendations are unlikely to result in expanded access for key populations unless special attention is paid to issues of equity, human rights and barriers that they face in accessing HIV and other health services. Notably, if access to ART for individuals from key populations in discordant couples is to become a reality, quality couples-based HIV testing and counselling must be expanded to MSM, PWID, sex workers, transgender people, prisoners, migrants and their primary partners.

### **HIV testing and counselling**

The 2013 guidelines affirmed existing WHO guidance<sup>85</sup> that in health facilities in generalized epidemics, provider-initiated HIV testing and counselling is recommended for key population groups, including people who inject drugs and their partners, MSM, transgender people, sex workers and prisoners. In health facilities in low and concentrated epidemic settings, provider-initiated HIV testing and counselling “should be considered” in services for sexually-transmitted infections, hepatitis and TB, antenatal care settings and services for key populations. A new recommendation in the 2013 guidelines provides that, in *all* HIV epidemic settings,

community-based HIV testing and counselling should be provided for key populations, including adolescents from key population groups, with appropriate linkage to prevention, care and treatment services. This recommendation recognizes that many people from key populations are unlikely to access HIV testing in health facilities. The guidelines also recognize that HIV testing among key populations - especially those who are criminalized - may sometimes be undertaken in punitive or coercive ways, and emphasize the importance of informed consent and maintaining confidentiality of test results.

### **Pre-exposure prophylaxis (PreP)**

The 2013 ARV guidelines affirmed existing WHO guidance<sup>86,87,88</sup> that, where serodiscordant couples are identified and where additional prevention choices are needed, daily oral PreP may be considered as a possible intervention for the uninfected partner. The recommendation also applies to men and transgender women who have sex with men. In each case, WHO suggested that PreP initially be offered on a limited basis through “demonstration projects”. In 2014, consolidated WHO guidance for key populations affirms these recommendations, while expanding the potential use of PreP for these populations beyond demonstration projects. In summary, PreP is now recommended as an option for serodiscordant couples and men and transgender women who have sex with men, but is not specifically recommended for other key population groups.

In many countries, new clinical recommendations for ART are unlikely to result in expanded access for key populations unless special attention is paid to equity and human rights.





### ***Post-exposure prophylaxis (PEP)***

PEP is the use of antiretroviral drugs after a single high-risk HIV exposure to prevent HIV infection. It has been widely used for occupational (such as health care provider) exposures to HIV, in cases of sexual assault, or in other acute, one-time exposures. PEP has also been used in some countries for some key populations, including MSM and sex workers. PEP must be started as soon as possible to be effective, and always within 72 hours (three days) of a possible HIV exposure. Two to three ART drugs are usually prescribed and must be taken for 28 days. These realities have limited the wide use of PEP as a prevention tool, but there is considerable evidence for its effectiveness in HIV-exposed individuals.

While PEP is an important prevention tool, it cannot substitute for use of other proven HIV prevention methods, such as consistent condom use or use of sterile injecting equipment.<sup>89</sup> However, PEP services may be an effective entry point for accessing these methods and other prevention services.

As PrEP becomes more widely available and more widely used, the interactions of PEP and PrEP will likely challenge individuals, communities and providers. A repeat PEP user who reports multiple exposures or requests repeated rounds of PEP is likely to be a better candidate for PrEP, which has better safety, toxicity, and efficacy profiles for regular - rather than one-time - use.



## 5. *Protecting rights and addressing barriers for key populations*

All people, including key populations, have the right to the highest attainable standard of physical and mental health, including access to HIV prevention and treatment. They also have the same rights as other people to freedom from discrimination, due process, equality before the law, privacy and the right to share in the advances of science.<sup>90</sup> Yet, in many countries, these rights are not protected or upheld for key populations, and stigma, discrimination and criminalization significantly increase their vulnerability to HIV and limit their access to HIV services.

### ***Stigma and discrimination***

More than 120 countries have legislation that outlaws discrimination on the basis of HIV status, and 112 countries legally protect at least some populations based on their vulnerability to HIV.<sup>62</sup> But these laws are often ignored, poorly enforced or aggressively flouted, and key population groups face widespread stigma and discrimination in the community, religious institutions, the media, health and social services, and at the hands of law enforcement agencies.

### ***Punitive laws, policies and practices***

Stigma and discrimination are frequently linked to and driven by criminalization of key populations. Same-sex activity is outlawed in around 80 countries, with penalties ranging from jail sentences to execution. MSM face harassment, arrest and police brutality in many countries that outlaw their behaviour and - despite their high biological and

social vulnerability to HIV - are frequently neglected in national HIV/AIDS strategies. Laws such as those recently passed in Uganda and Nigeria not only prevent MSM from gathering, organizing and accessing HIV-related information, but also compound existing stigma and expose them to the potential of further violence and ostracism in the community.

More than 100 countries explicitly criminalize some aspect of sex work, and many outlaw it entirely. Such laws effectively deny sex workers legal protection from assault and justify compulsory HIV and STI testing, involuntary medical examinations, arbitrary detention and other abuses. In many countries, both sex workers and MSM fear carrying condoms because they may be used as evidence against them.

The treatment of drug use as a criminal rather than public health issue exposes people who use drugs to similar discrimination, harassment, police brutality and high rates of incarceration in most regions and the vast majority of countries. In many Eastern European and Central Asian countries, people who use drugs are named on registers that stigmatize them, often for life, and may result in loss of employment, denial of child custody and other punitive measures. In Southeast Asia, hundreds of thousands of people who use drugs are arbitrarily detained in "rehabilitation" centres that systematically abuse human rights, impose harsh conditions and offer no treatment for drug dependence. Legal frameworks continue to limit access to

All people, including key populations, have the right to the highest attainable standard of physical and mental health.



comprehensive harm reduction, including OST and adequate needle and syringe exchange in a large number of countries. Notably, methadone remains illegal in Russia, and previously existing methadone and buprenorphine programmes have been closed in Crimea since its annexation in 2014.

In many countries, transgender people are denied acknowledgement as legal persons, limiting their access to health and social services<sup>91</sup>. Transgender people also frequently bare the brunt stigma, discrimination, police brutality and other rights abuses.<sup>92,93,94</sup>

Around 70 countries criminalize exposing another person to HIV, especially through sex. However, there is no evidence that laws criminalizing HIV non-disclosure, exposure or transmission are effective in regulating the conduct of people living with HIV or promoting safer sex practices. On the contrary, evidence suggests that such laws and prosecutions do more harm than good by creating additional barriers to accessing HIV testing, treatment, care and support<sup>95,96</sup> and they rarely take into account the impact of ART in reducing transmission risk.

Some countries have begun to implement “smart” policing approaches involving training for police officers in HIV prevention and drug use, but these remain lamentably rare.<sup>97</sup>

The widespread failure to respect human rights obligations to key populations and inadequate legal mechanisms to protect them must be challenged by health professionals, national policymakers, caregivers, service providers, communities and scientists. All stakeholders in

the HIV response need to be concerned that key populations have access to evidence-based programmes and are treated with dignity and respect.

### *Issues for adolescents and young adults*

Particular attention is needed to address the challenges faced by adolescents and young adults from key populations, among whom HIV infections continue to rise alarmingly. Young people aged 10 to 24 years comprise one-quarter of the world’s population.<sup>98</sup> In 2012, nearly 5 million people aged 15–24 years were living with HIV,<sup>99</sup> accounting for more than 40% of all new infections worldwide in people over 15 years of age.<sup>100</sup> Young people who are part of one or more key populations are especially vulnerable to HIV due to factors such as power imbalances in relationships, entering sex work at puberty or early adolescence, starting gender-affirming changes without clinical supervision, or inappropriate institutionalization. They may also be less likely to access health services, and when they do access them, health providers are frequently not equipped to understand and address their needs. These factors increase the risk that they may engage in behaviours that put them at risk of HIV, such as unprotected sex and alcohol and drug use. Young people from key populations are also made more vulnerable by policies and laws that criminalize them or their behaviours and by education systems that frequently fail to provide information and support concerning sex, relationships and drug use.

Age of consent laws in many countries may prevent adolescents and young adults

Particular attention is needed to address the challenges faced by adolescents and young adults from key populations.



from making autonomous decisions about their own health, impeding their ability to access HIV treatment and prevention. WHO has specifically encouraged countries to review their age of consent laws where appropriate and to take other steps to ensure that HIV services are adolescent-friendly, including appropriate training for health workers and provision of financial and community-based support services that are tailored to adolescent needs.

### ***Treatment first, with informed consent***

Rights-based approaches to ART recognize that the primary objective of ART should be to treat the HIV-infected person; the prevention benefits of treatment are an important, secondary consideration. As with all medical interventions for all people, the provision of ART to key populations must be non-coercive and health care providers must always ensure that informed consent is voluntarily given and that patient confidentiality is maintained.

### ***Improving data on key populations***

Data on key populations, including population size estimates and data relating to access and barriers to services, remain very limited in many countries. A key strategy to ensure that programmes for key populations are adequately financed and available is implementing measures to capture better data about key population groups, including, where possible, through national HIV surveillance systems. Such systems should include appropriate safeguards to ensure that individuals in key population groups retain anonymity, and that their safety, security and human

rights are not jeopardized in the course of data collection processes. Where national surveillance systems fail to capture such data or in places where size estimation and mapping exercises pose a threat to safety, community organizations - if adequately resourced - can play an important role in data generation.

### ***Trade and intellectual property barriers***

The Global Commission on HIV and the Law has identified a number of persistent challenges in the global intellectual property regime that continue to threaten access to ART and other medicines in low- and middle-income countries. While they are important, so-called TRIPS flexibilities have been used by relatively few countries, and some of these countries have experienced retaliation for doing so. TRIPS flexibilities also offer limited assistance to countries that face patent barriers but do not have their own ARV manufacturing capacity and are therefore still dependent on importing medicines from countries where TRIPS rules limit exports to insufficient quantities. Significantly, a number of free trade and anti-counterfeiting agreements propose to impose even more burdensome conditions on countries' abilities to access patented medicines (so-called "TRIPS-plus" conditions). Such proposals create serious tensions between governments' commitments to HIV and human rights and their commitments and agreements on trade. They may be of particular concern in countries with epidemics concentrated among key populations that often comprise the majority of people living with HIV needing access to ART through public health systems.

Rights-based approaches to ART recognize that the primary objective of ART should be to treat the HIV-infected person; the prevention benefits of treatment are an important, secondary consideration.



### **Key elements of rights-based approaches**

In contrast to the approaches taken in many countries, measures that promote and protect human rights, reduce barriers to accessing services and empower and involve key populations in the HIV response (also known as “critical enablers”), will all contribute to achieving universal access to ART.

Key elements of rights-based approaches and measures to address critical enablers among key populations include the following:

- **Creating an enabling legal environment:** This includes laws that protect people from discrimination on the basis of actual or perceived health status, together with appropriate enforcement mechanisms; non-criminalization of involuntary HIV transmission and sex work; repeal of laws that criminalize same sex behaviour and prevent MSM from gathering, organizing and gaining access to HIV-related information and services; repeal of laws that criminalize and discriminate against transgender people based on their gender identities and expressions; measures to address drug use as a public health rather than a criminal issue, including decriminalization of possession of illicit drugs and other alternatives to ineffective and harmful laws based on current international drug control conventions; measures to authorize the provision of key HIV prevention interventions in prison settings, including condoms, OST, and needle and syringe exchange; legal recognition and access to services for migrant

populations; closure of “rehabilitation” centres for people who use drugs and sex workers; removal of the legal obligation of health workers to report people who use drugs and sex workers to the authorities; legal recognition of transgender people’s gender identities and full access to transitional health care compatible with human rights standards, including depathologization of transgender people;

- **Implementing measures to combat stigma and discrimination and to reduce violence against key populations, including training for health care providers, police, judiciary, community and religious leaders, and the media;**
- **Community mobilization and participation:** Empowering key populations to meet, organize, share information, advocate for their rights and participate in policy development and service delivery through local and national mechanisms. Meaningful participation includes enabling key populations to choose whether and how to participate, how they are represented and by whom.
- **Increasing accessibility of services:** Community-based HIV testing and prevention and treatment literacy, with links to non-judgmental care and support; “Know your Rights” and access to justice initiatives, including legal aid services.



## **6. Time for action on ART for key populations**

This paper provides clear evidence that key populations account for a significant proportion of the global burden of HIV, and that epidemics among key populations are characterized by extraordinarily high prevalence rates and remarkably low levels of access to HIV treatment and prevention in all regions, countries and epidemic types. Donors and implementing countries alike need to be held accountable for their 30-year failure to ensure that interventions and services reach the people who need them most. Unless dramatic action is taken to improve access to ART and other key interventions for men who have sex with men, people who inject drugs, sex workers and transgender people, and to more effectively meet the health needs of prisoners and migrant populations, there can be little hope of ending the HIV epidemic.

Consistent with the Melbourne Declaration of 2014\*, the international community must act with urgency to ensure that:

- There is sustained advocacy to increase political will and commitment to tackling the global HIV crisis among key population groups;
- Governments prioritize the needs of key populations in national AIDS strategies;
- There is increased domestic and international funding to enhance ART access for key populations, address critical enablers, implement rights-based approaches and reduce legal and human rights barriers to ART access, including criminalization of same-sex activity, sex work and drug use;
- Particular efforts are made to ensure that adequate domestic and/or international resources are available to support interventions for key populations in middle-income countries and emerging economies;
- Expanded access to ART occurs in the context of comprehensive care and prevention, including comprehensive harm reduction and tailored prevention programming for PWID, MSM, sex workers and transgender people, recognizing that these approaches are all essential to achieving maximum impact on the epidemic;

Unless dramatic action is taken to improve access to ART and other key interventions for men who have sex with men, people who inject drugs, sex workers and transgender people, and to more effectively meet the health needs of prisoners and migrant populations, there can be little hope of ending the HIV epidemic.

\* Annexed to this paper.



- There is recognition that interventions for key populations are most effectively delivered through community- and peer-based organizations, and that these organizations are adequately funded and effectively linked to health services;
- There is increased attention to capturing data on key populations, including population size estimates, through both national systems and community-based efforts that are adequately resourced;
- The international community remains vigilant to ensure that the current attention being paid to key populations by international organizations, donors and advocacy groups is sustained in the post-2015 HIV and development agenda, and translates into expanded programming, enhanced access to ART and greater impact on HIV transmission and HIV and health outcomes for key population groups.



## AIDS 2014 MELBOURNE DECLARATION Nobody left behind

*“All human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood.”*

Article 1, Universal Declaration of Human rights, 1948.

We gather in Melbourne, the traditional meeting place of the Wurundjeri, Boonerwung, Taungurong, Djajawurrung and the Wathaurung people, the original and enduring custodians of the lands that make up the Kulin Nation, to assess progress on the global HIV response and its future direction, at the 20th International AIDS Conference, AIDS 2014.

We, the signatories and endorsers of this Declaration, affirm that non-discrimination is fundamental to an evidence-based, rights-based and gender transformative response to HIV and effective public health programmes.

To defeat HIV and achieve universal access to HIV prevention, treatment, care and support – nobody should be criminalized or discriminated against because of their gender, age, race, ethnicity, disability, religious or spiritual beliefs, country of origin, national status, sexual orientation, gender identity, status as a sex worker, prisoner or detainee, because they use or have used illicit drugs or because they are living with HIV.

We affirm that all women, men, transgender and intersex adults and children are entitled to equal rights and to equal access to HIV prevention, care and treatment information and services. The promotion of gender equity is essential to HIV responses that truly meet the needs of those most affected. Additionally, people who sell or who have sold sex, and people who use, or who have used illicit drugs are entitled to the same rights as everyone else, including non-discrimination and confidentiality in access to HIV care and treatment services.

We express our shared and profound concern at the continued enforcement of discriminatory, stigmatizing, criminalizing and harmful laws which lead to policies and practices that increase vulnerability to HIV. These laws, policies, and practices incite extreme violence towards marginalized populations, reinforce stigma and undermine HIV programmes, and as such are significant steps backward for social justice, equality, human rights and access to health care for both people living with HIV and those people most at risk of acquiring the virus.



## AIDS 2014 MELBOURNE DECLARATION Nobody left behind

In over 80 countries, there are unacceptable laws that criminalize people on the basis of sexual orientation. All people, including lesbian, gay, bisexual, transgender and intersex people are entitled to the same rights as everyone else. All people are born free and equal and are equal members of the human family.

Health providers who discriminate against people living with HIV or groups at risk of HIV infection or other health threats, violate their ethical obligations to care for and treat people impartially.

**We therefore call for the immediate and unified opposition to these discriminatory and stigmatizing practices and urge all parties to take a more equitable and effective approach through the following actions:**

- Governments must repeal repressive laws and end policies that reinforce discriminatory and stigmatizing practices that increase the vulnerability to HIV, while also passing laws that actively promote equality.
- Decision makers must not use international health meetings or conferences as a platform to promote discriminatory laws and policies that undermine health and wellbeing.
- The exclusion of organisations that promote intolerance and discrimination including sexism, homophobia, and transphobia against individuals or groups, from donor funding for HIV programmes.
- All healthcare providers must demonstrate the implementation of non-discriminatory policies as a prerequisite for future HIV programme funding.
- Restrictions on funding, such as the anti-prostitution pledge and the ban on purchasing needles and syringes, must be removed as they actively impede the struggle to combat HIV, sexually transmitted infections, and hepatitis C among sex workers and people who inject drugs.
- Advocacy by all signatories to this Declaration for the principles of inclusion, non-criminalization, non-discrimination, and tolerance.

In conclusion we reaffirm our unwavering commitment to fairness, to universal access to health care and treatment services, and to support the inherent dignity and rights of all human beings. All people are entitled to the rights and protections afforded by international human rights frameworks.

An end to AIDS is only possible if we overcome the barriers of criminalization, stigma and discrimination that remain key drivers of the epidemic.

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